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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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KRAMER LEVIN NAFTALIS & FRANKEL LLP
INTELLECTUAL PROPERTY DEPARTMENT
1177 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER	
ALLEN, MARIANNE P	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 04/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/045,534	PILON, APRILE L.	
	Examiner	Art Unit	
	Marianne P. Allen	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-15,34,35 and 40-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-15,34,35 and 40-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments filed 922/05 have been fully considered but they are not persuasive.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1-5, 7-15, 34-35, and 40-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 1, 9, and 34 have been amended to recite that the candidate compound is selected from the group consisting of fragments of uteroglobin. No specific basis has been pointed to and none is apparent, particularly where fragments of uteroglobin compete for binding with a uteroglobin-like compound. (See for example claims 4-5.)

New claims 40-54 also recite limitations where the candidate compound is selected from the group consisting of fragments of uteroglobin. As set forth above, this is considered to be new matter. In addition, basis for the methods set forth in these claims is not seen. Applicant states in the response that basis is found in original claims 1-15 and 34-35; however, this is not agreed with. For example, new claim 40 requires two determination steps. There does not appear to be a disclosure of a method with these two steps. Note also that the preamble of claim 40 is directed at "identifying compounds capable of at least one of ..." but that the steps are

directed to determining inhibitors and not compounds capable of causing the effects of the preamble. Similarly, claims 46 and 48 require three and two determination steps, respectively. There does not appear to be a disclosure of methods with these combinations of steps.

Claims 1-5, 7-15, 34-35, and 40-54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods as set forth below, does not reasonably provide enablement for all methods embraced by the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

As set forth in the prior Office action "fibronectin Type III polypeptide" embraces many proteins. Not all of the polypeptides encompassed by the claims are involved in fibronectin-mediated processes such as fibronectin-mediated cell adhesion. The specification is enabled for fibronectin or superfibronectin but not any polypeptide comprising an fnIII domain.

Applicant's arguments are unpersuasive and circular. The specification enables only identifying compounds that competitively bind to fibronectin or superfibronectin in the presence of uteroglobin.

Claims 1-5, 7-15, 34-35, and 40-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is indefinite in depending upon cancelled claim 6.

Claim 40 is confusing because while the preamble of the method is directed to "identifying compounds capable of at least one of ..." the steps are directed to determining inhibitors and not compounds capable of causing the effects of the preamble. Furthermore, there is no association between steps (a) and (b). These appear to be independent steps where the information found in step (a) is not used by step (b). Step (a) recites "inhibits a fibronectin mediated response" and step (b) recites "inhibits cell adhesion, binds fibronectin or binds superfibronectin" which are inconsistent with the "fibronectin-dependent cell adhesion, polymerization, deposition or fibronectin-fibronectin interactions" of the preamble.

Claim 46 is confusing in that there is no association between steps (a), (b), and (c). These appear to be independent steps where the determination in step (a) is not used by any other step. The contacting of step (b) does not appear to result in any information used by the method to make any kind of determination. Step (a) recites "inhibits a fibronectin mediated response" and step (c) recites "inhibits cell adhesion, binds fibronectin or binds superfibronectin" which are inconsistent with the "fibronectin-dependent cell adhesion, polymerization, deposition or fibronectin-fibronectin interactions" of the preamble.

Claim 48 is confusing in that there is no association between steps (a) and (b). These appear to be independent steps where the information found in step (a) is not used by step (b). Step (a) recites "inhibits a fibronectin mediated response" and step (b) recites "inhibits cell adhesion, binds fibronectin or binds superfibronectin" which are inconsistent with the "fibronectin-dependent cell adhesion, polymerization, deposition or fibronectin-fibronectin interactions" of the preamble. It is noted that claim 48 contains two periods (".") at the end of the claim.

Claims 7, 14, 45, and 53 are confusing in that it is unclear whether the "fragments of uteroglobin" the "uteroglobin-like compound" or both are recombinant human uteroglobin.

Claims 1-5, 7, 9-14, and 34-35 remain indefinite in reciting "fibronectin-mediated processes" as the specification does not define these processes. Applicant's arguments are unpersuasive. The examples pointed to by applicant are not limiting and the specification fails to provide the metes and bounds of what was intended to be encompassed.

Claim Rejections - 35 USC § 102

As set forth in the prior Office action, applicant has claimed priority to parent applications 09/835,784; 09/549,926; 09/120,26; 09/087,210; and 08/864,357; however, applicant is denied benefit of these filing dates because none of the parent applications disclose the methods presently claimed. Applicant is entitled only to benefit of the instant filing date, 24 October 2001. Should applicant argue otherwise, they are obligated to point to basis and support in every parent application for the presently claimed methods.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhang et al. (*Science*, 276:1408-1411, 30 May 1997).

The specification defines "fragment" of uteroglobin on page 20 of the specification to include amino acid sequences having six or more contiguous amino acids of the native protein. This definition does not exclude the full length protein.

Zhang et al. (*Science*, 276:1408-1411, 30 May 1997) discloses determining whether recombinant uteroglobin binds to fibronectin. Inhibition of fibronectin-mediated processes such as Fn-Fn interactions are disclosed. A competitive binding assay is used. See Figures 3B-F and pages 1410-1411.

Claims 1-5, 7-15, 34-35, and 40-54 are rejected under 35 U.S.C. 102(a) as being anticipated by Farrow et al. (*Annals of the NY Academy of Sciences*, 923:338-342, December 2000).

The specification defines "fragment" of uteroglobin on page 20 of the specification to include amino acid sequences having six or more contiguous amino acids of the native protein. This definition does not exclude the full length protein.

Farrow et al. (*Annals of the NY Academy of Sciences*, 923:338-342, December 2000) discloses determining whether recombinant uteroglobin binds to fibronectin and determining whether recombinant uteroglobin can inhibit cell adhesion of NIH 3T3 cells to human fibronectin. A competitive binding assay is used. Unlabeled uteroglobin displaces labeled uteroglobin from binding to a complex of uteroglobin and fibronectin. See at least introduction, Table 1 and Figure 1.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marianne P. Allen
Primary Examiner
Art Unit 1647

4/11/06

mpa